EXHIBIT E

Non-Responsive

Deliberative Process

Non-Responsive

Deliberative Process

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Non-Responsive

From: Wiack, Michael
To: Lias, Courtney H; Kelm, Kellie; Grove, Andrew D
Cc: Gutierrez, Alberto; Hojvat, Sally A; Chan, Yung; Lovell, Stephen; Scherf, Uwe; El Mubarak, Haja Sittana
Subject: RE: Theranos TSPU & TLAS Procode and/or applicable regulation
Date: Thursday, November 20, 2014 3:26:05 PM

Deliberative Process

This is how they describe it:

These automated processes conducted by the TSPU are analogous to the preanalytic sample preparation performed by a
phlebotomist/lab technician in a service center, and include sample processing operations such as sample separation and addition of various reagents, as well as automated specimen acceptability and rejection processes (with multiple redundancies added in an automated manner). It is important to note that the automation of the preanalytic sample processing eliminates common human error in sample preparation and processing, a significant factor in laboratory test error rates.

The next operation performed by the TSPU is digital transmission of preanalytic specimen data to the Theranos CLIA-certified laboratory for analytic testing and post analytic processing. Again, this operation is analogous to a patient specimen collection site in which the collected and preanalytic processed sample would be physically transported to a CLIA certified laboratory for analytic and post analytic processing. However, in this case, rather than transporting the physical sample, the TSPU transmits data on the specimen to the Theranos CLIA laboratory for analytic testing and post-analytic processing via the TLAS.

Deliberative Process

Michael

From: Lias, Courtney H
Sent: Thursday, November 20, 2014 7:56 AM
To: Wiack, Michael; Kelm, Kellie; Grove, Andrew D
Cc: Gutierrez, Alberto; Hojvat, Sally A; Chan, Yung
Subject: RE: Theranos TSPU & TLAS

Thanks Michael –

Deliberative Process

Deliberative Process

Thanks,

Courtney

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health
Food and Drug Administration
Ph 301-796-5458

From: Wiack, Michael
Sent: Wednesday, November 19, 2014 4:02 PM
To: Kelm, Kellie
Cc: Chan, Yung; Lias, Courtney H
Subject: RE: Theranos TSPU & TLAS

I asked Andy to add this to the agenda for next Mondays instrument/software meeting. I just want to be sure that all these issues are fully vetted office-wide.

From: Kelm, Kellie
Sent: Wednesday, November 19, 2014 11:53 AM
To: Wiack, Michael
Cc: Chan, Yung; Lias, Courtney H
Subject: RE: Theranos TSPU & TLAS

Michael,

I've cc'd Yung and Courtney. **Deliberative Process**

Deliberative Process

Kellie

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From: Wiack, Michael
Sent: Wednesday, November 19, 2014 10:25 AM
To: Kelm, Kellie
Subject: Theranos TSPU & TLAS

Hi Kellie,

I know you were extensively involved in several Theranos Pre-subs. Do you remember if the issue of what product code/regulation(s) would cover the TSPU-TLAS?
We have a 510k in DMD for their HSV-1 assay and I'm reviewing the software.

Thanks

Michael Wiack
Scientific Reviewer
CDRH/OIR/DMD
301-796-6209

From: Pilcher, Ian
To: Gutierrez, Alberto; Lias, Courtney H
Subject: Law Enforcement
Date: Monday, January 25, 2016 4:46:31 PM

I just saw another WSJ article on Theranos, which Law Enforcement This article stated that CMS has found more issues at Theranos that are more serious than those found in their earlier inspections. Do we know about this CMS inspection and what they found? The article also makes some statements about whether or not the "Edison" systems were ever in use. Theranos has consistently told us that they were not in us. If there is anything that you think I should pass on to OCI about any of these, please let me know.

Thanks,

Ian